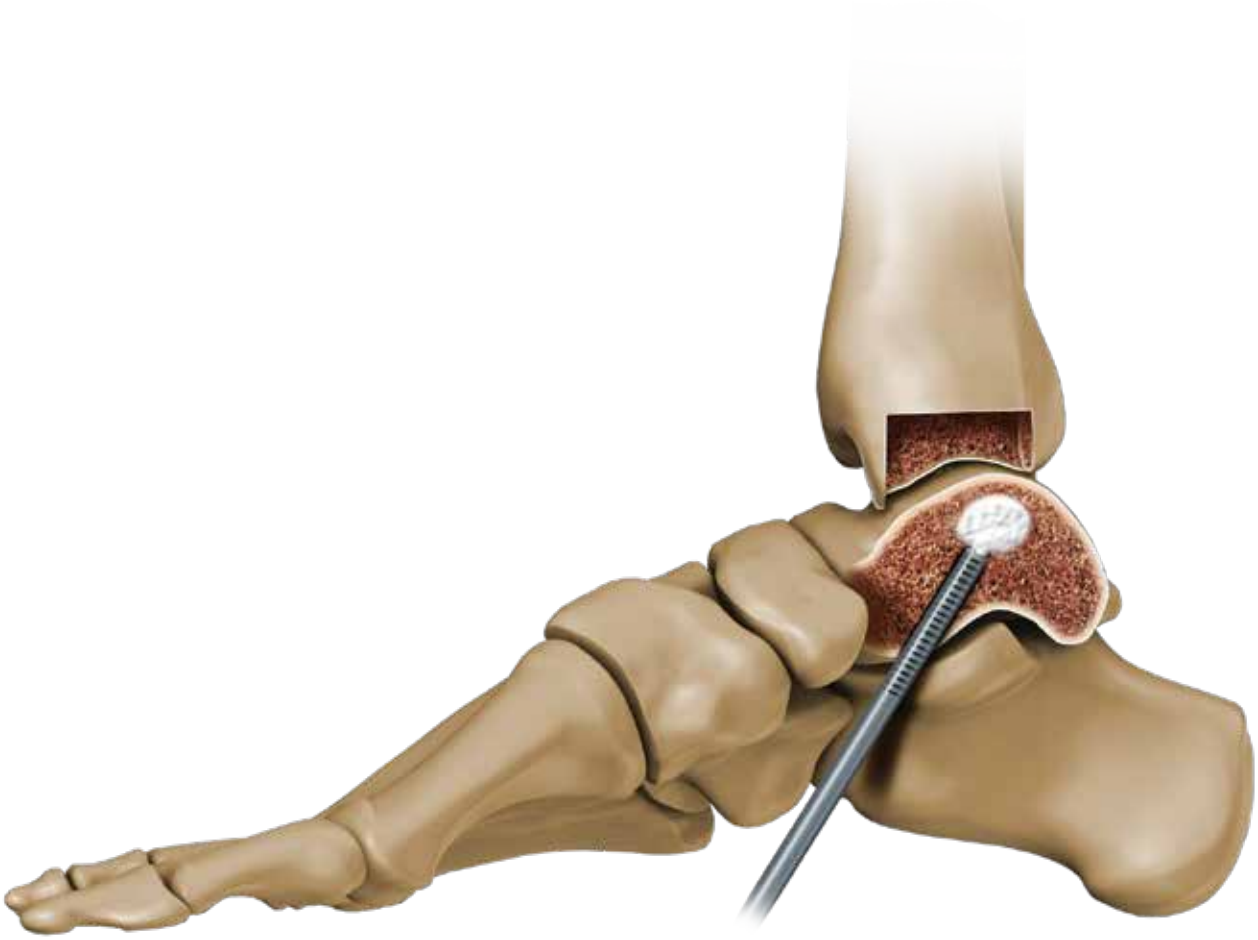
The Subchondroplasty® (SCP®) Procedure for Foot & Ankle

Surgical Technique



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Symbols Convention

This document employs the following conventions:

NOTE: This symbol is present to provide a general observation or information to procedures, events or practices which are recommended or essential for a successful operation.

CAUTION: This symbol indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

WARNING: This symbol is present when a warning alerts you to a potential danger to health or life.

The Subchondroplasty® (SCP®) Procedure

The Subchondroplasty Procedure is a minimally-invasive, fluoroscopically-assisted procedure that targets and fills subchondral bone defects, often called bone marrow lesions (BML), with AccuFill® PF Bone Substitute Material (BSM), a hard-setting, biomimetic bone substitute. The procedure is performed along with arthroscopy of the affected knee, to assess the extent of the tibial plateau injury, assist in targeting the underlying plateau defect, and visualize and treat other structures inside the joint.

The Subchondroplasty Procedure consists of four components:

PREOPERATIVE PLAN: Identify the BML bone defect using a T2 and T1 MRI plan approach and trajectory based on defect location.

TARGET THE BONE DEFECT: Using arthroscopy and intraoperative fluoroscopy, localize the bone defect relative to the T2 and T1 MRI findings.

ACCESS THE DEFECT: Drill the appropriate AccuPort® Delivery Cannula to the bone defect.

FILL THE BONE DEFECT: Inject AccuFill BSM into the subchondral bone defect based on the T1 image.

AccuFill BSM Indications for Use:

AccuFill Bone Substitute Material is an injectable, self-setting, macroporous, osteoconductive, calcium phosphate bone graft substitute material that is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e., posterolateral spine), and the pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. AccuFill BSM is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Features and Benefits

The Subchondroplasty (SCP) Procedure

The SCP Procedure is a treatment option for chronic bone defects, including BML, not responsive to conservative care.*

The SCP Procedure fills closed bone defects with AccuFill BSM, an injectable bone substitute material. The AccuFill BSM mimics the composition of inorganic bone material. It is replaced with new bone during the healing process.[2,4,**]

AccuFill Bone Substitute Material (BSM)

The injectable Calcium Phosphate (CaP) for the SCP Procedure

Criteria	Features	Benefits
Formulation	Proprietary engineered apatite Chemically similar to apatite of bone[1]	Undergoes cell-mediated remodeling[2,4]
Handling	Injectable[2,3] Remains cohesive[2,3] Flowable inside cancellous bone[2,3] 15 minutes of working time at 25°C[1,5]	No need to remove subchondral bone No phase separation from injection pressure[2,3] Interdigitates easily for complete defect fill[2,3] Extended time frame for implantation Intraoperative flexibilty
Setting	Sets in 10 minutes at 37°C[5]	Sets hard, no thermal necrosis
Structure	Osteoconductive Nanocrystalline structure[1,***] 55% total porosity; 1 to 300 µm pore size[2] 7 to 9 MPa compressive strength[2]	Physical properties comparable to that of cancellous bone[1]
Remodeling	Cell-mediated remodeling[2,4,**] Remodeled vs. dissolved[2,4,**]	Remodels with new bone growth[2,4,**]

1 TRE_061017, Characterization of CaP-Porous Material ; 15-Sep-2006, ETEX Corporation (Internal document)

2 Angle SR, Strunk MR. Novel Macroporous Calcium Phosphate Scaffold To Improve Cell Infiltration and Osseous Integration. Transactions of the 61st Annual Meeting of the Orthopaedic Research Society: 1157, 2015*, ****

3 Colon DA, Yoon BJV, Russell TA, Cammisa FP, Abjornsen C. Assessment of the injection behavior of commercially available bone BSMs for Subchondroplasty procedures. Knee. 2015; 22(6):597-603.

4 Welch R.D 2018 : Rabbit Femoral Core Defect Histology Evaluation : ETEX Study # 104-0621. ****

5 OssiPro K062630 (510(K) internal document)

* Bone Marrow Lesions (BML) and Bone Marrow Edema (BME) are often used interchangeably to identify subchondral bone defects like microtrabecular or insufficiency fractures.

** Animal studies are not necessarily indicative of clinical outcomes.

*** The grain size of the hydroxyapatite (HA) crystals that form as part of the amorphous and crystalline mixture of calcium phosphate sets are on the nanometer scale. The size of the crystalline structures were measured by x-ray diffraction to be less than 100 nanometers.

**** based on calcium phosphate Alpha-BSM

Preoperative Planning

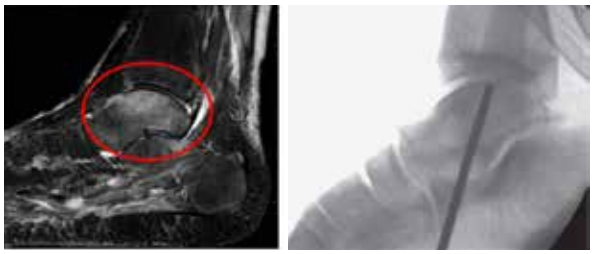
The SCP Procedure treats chronic subchondral bone defects, often called bone marrow lesions (BML), by injecting AccuFill BSM into the defect. The SCP Procedure targets and fills osseous defects in the forefoot, midfoot, and hind foot. The presence and location of the BML is identified with fat suppressed MRI (e.g., T2FS, T1FS). BML defects are not visible on intraoperative fluoroscopy.

To accurately inject the AccuFill BSM with a minimally-invasive technique, the surgeon must determine the location of the bony defect relative to radiographic landmarks, using the patient's MRI.

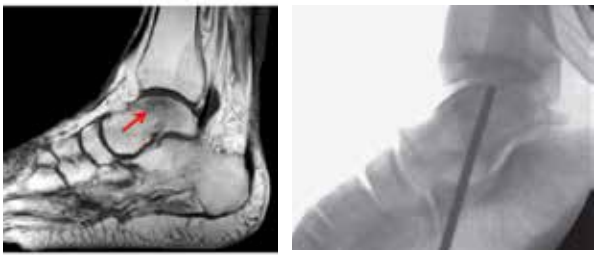
This preoperative plan is then used intraoperatively to target the defect with fluoroscopy, for optimal AccuFill BSM implantation.

Localize the BML on fat-suppressed T2 MRI slices

- Use two or more planes to determine:
  - Position on coronal and sagital views
  - Distance from joint
  - (Depth) superficial or deep to cortex T1 image defect location.
- Plan approach and trajectory based on defect location.
- Determine which AccuPort Cannula will be used: 11 ga end-targeting, or 15 ga end-targeting. 11 ga side-targeting (used in calcaneal defects)
- The Subchondroplasty Procedure may be performed with arthroscopy, for visualization and treatment of structures inside the joint. Arthroscopy may be performed before or after the SCP Procedure.
- For midfoot and forefoot bones, where scoping is not possible, an open approach will allow direct visualization of the bone.



T2 Image (Smoke)--> To diagnose bone marrow lesion / Stress Fx



T1 Image (Fire)--> To target and inject accurate volume

AccuPort Cannula & AccuFill BSM Volume Suggestions*

Bone	Cannula	Volume
Talus	11 ga End	**0.5 - 1.0** cc
Distal Tibia	11 ga Side or End	**1.0** - 2.0 cc
Calcaneus	11 ga End or Side	**1.0** - 2.0 cc
Cuneiforms	15 ga	**0.3** - 0.5 cc
Cuboid	15 ga or 11 ga End	**0.5** - 1.0 cc
Forefoot	15 ga	**0.25** - 0.5 cc

* F&A Advisory Group suggestions, Meeting Notes 3/2016

NOTE: Volume determination will vary from patient to patient and is dependent on pathology and radiographic appearance.

Surgical Technique

The Subchondroplasty Procedure is usually performed with arthroscopy, for visualization and treatment of findings inside the joint. Arthroscopy may be performed before AccuFill BSM injection or after. Some surgeons prefer scoping first, to evaluate the joint cartilage and cortical bone adjacent to the BML before injecting AccuFill BSM into the subchondral bone defect.

NOTE: When scoping after BSM injection, however, note that the AccuPort injection cannulas must be left in the bone for 10 minutes while the BSM sets, to minimize potential for extravasation.

Care must be taken to avoid applying bending forces on the cannula while manipulating the ankle during scoping, to avoid damage to the cannula or surrounding bone.

Important Information: The use of AccuFill BSM is not intended to be intrinsic to the stability of the bony structure. Radiographic studies should be used to confirm that the adjacent cortical bone is intact.

OR Setup

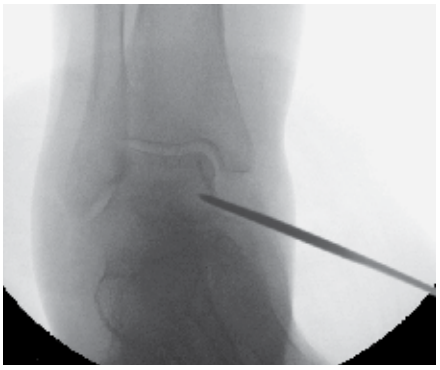
Position, prep, drape patient

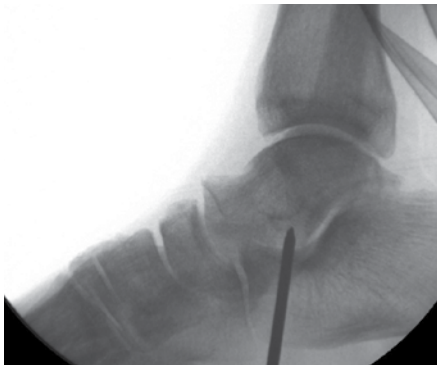
- The ankle should be positioned on a radiolucent table to allow for true anteroposterior (AP) / mortise and lateral views, and elevated by placement on a sterile bump for ease of obtaining a lateral fluoroscopic view.
- Prep and drape as for ankle arthroscopy.

NOTE: If performing arthroscopy or another procedure along with the SCP Procedure, position equipment such that C-Arm is easily accessible throughout the procedure.

Target the Defect

- Using intraoperative fluoroscopy, localize the bony defect relative to MRI findings.
- With the MRI as a reference, the cannula is triangulated into the defect, confirmed with AP/mortise and lateral views.



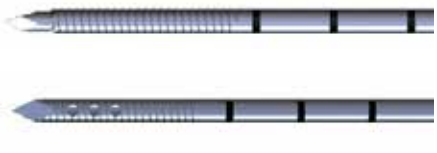


Access the Bone Defect

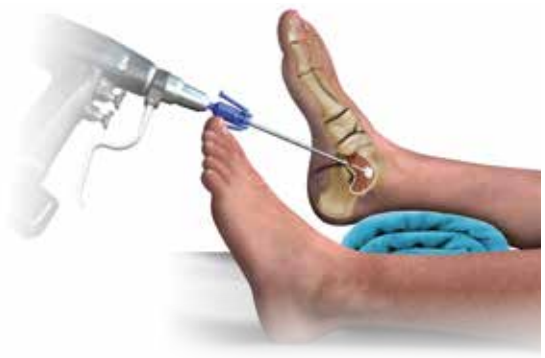
AccuPort Cannulas are available in both 11 ga (3.0 mm OD) and 15 ga (1.8 mm OD) sizes. The 11 ga cannula has two delivery options:

- Side-delivery: 3 side fenestrations for directed flow of BSM from alongside or margin of bone defect.
- End-delivery: End aperture for direct delivery of BSM into defect.

The 15 ga cannula is available in end-delivery only.



- Confirm starting position and trajectory of AccuPort Cannula under fluoroscopy.
- An incision may be made for insertion of the cannula.
- Using an orthopaedic wire driver, advance cannula to the cortex.
- Insert cannula into the bone. Confirm position with fluoroscopy.
- Drill the cannula to desired depth and location. Confirm position with AP and lateral fluoroscopy.

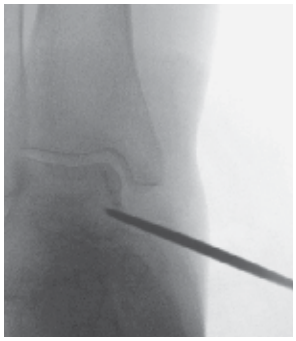


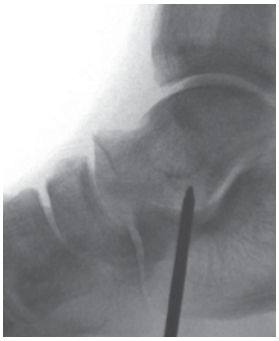
⚠ **CAUTION:** Ensure the AccuPort Cannula is inserted within the confines of the bone prior to injection. To minimize extravasation, the delivery holes of the cannula must be within the subchondral bone. Multiple drill paths into the bone are to be avoided as this may lead to extravasation of the AccuFill BSM.

⚠ **CAUTION:** Avoid excessive or prolonged drilling into bone as it may cause increased temperatures in cannula and surrounding bone. Before injection allow cannula to cool to body temperature.

Operative Tip:

- Set the surgical driver to the drill setting, not ream.
- Insert the drill to the hub of the AccuPort Cannula.
- If using the 15 ga AccuPort Cannula, the use of the sleeve limits the penetration depth of the 15 ga AccuPort Cannula to 6 mm.





NOTE: Allow AccuPort to cool prior to injection of the

Implant Placement: Filling the Bone Defect

Mixing Option 1: Using the AccuMix system / SCP Complete Kit

AccuFill BSM is hydrated and mixed before injection, using normal saline (0.9%). The material is mixed using the AccuMix mixing system, a closed syringe device. Allow for mixing time while avoiding down time after cannula insertion. Working time for AccuFill BSM is approximately 15 minutes (maximum time between mix and injection) and mixed material will not set until injected into the patient.

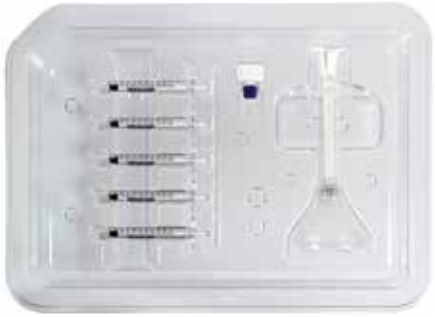
AccuMix Mixing System

AccuMix syringe mixing provides closed mixing of AccuFill BSM with its hydrant and closed transfer to injection syringes. The AccuMix mixing syringe acts as both mixer and transfer syringe, and couples to injection syringes with a standard luer-lock connection.

AccuFill BSM Mixing Technique Setup:

The AccuMix system tray (AccuMix system or SCP Complete Kits) is sterile and provides stability for the mixing syringe during BSM powder transfer.

1. Transfer the tray to the sterile field (back table). Remove the mixing syringe and set upright in the tray groove; lift funnel to extend syringe.
2. Remove vial of AccuFill powder from jar. Empty powder into funnel; tap until powder enters syringe.



3. Remove funnel; fully tighten cap and plug. Remove blue plug and set in sterile tray. **DO NOT DISCARD PLUG!**

NOTE: Do not empty entire 10 ml of saline vial into AccuFill BSM powder. Measure and use only the exact volume noted below.

Hydrate:

4. Using standard technique, connect the saline syringe and adaptor to the saline vial, injecting air into the saline vial and then draw back the desired amount of saline.

   – 5 cc AccuFill BSM
   - 3.0 cc saline
   - Alternative: 3.4 cc whole blood

   – 3 cc AccuFill BSM
   - 2.0 cc saline
   - Alternative: 2.3 cc whole blood

Implant Placement: Filling the Bone Defect (cont.)

AccuFill BSM Mixing Technique

5. Connect saline syringe to white cap; tighten. Inject saline briskly into powder; pull up on syringe plunger to pull excess air into saline syringe. Inject again, to ensure ALL SALINE FLOWS INTO POWDER, then repeat to release pressure.
6. Remove saline syringe; set it in the sterile tray. Attach blue plug to cap.

Mix:

7. Tilt mixing syringe toward you to remove from the tray. Remove plunger sleeve from plunger stem. DO NOT DISCARD SLEEVE!
8. Thoroughly mix powder and saline for 60 strokes (~60 seconds), **MIXING THE FULL LENGTH OF THE CYLINDER.** Twist and rotate while plunging until mix takes "toothpaste" consistency.
9. Reattach sleeve to stem, with stem fully extended. Remove blue plug.

Transfer:

10. Holding syringe with white cap upright, expel excess air from syringe, pushing the plunger approximately 2/3rds up the cylinder until you can visualize the Accufill BSM.

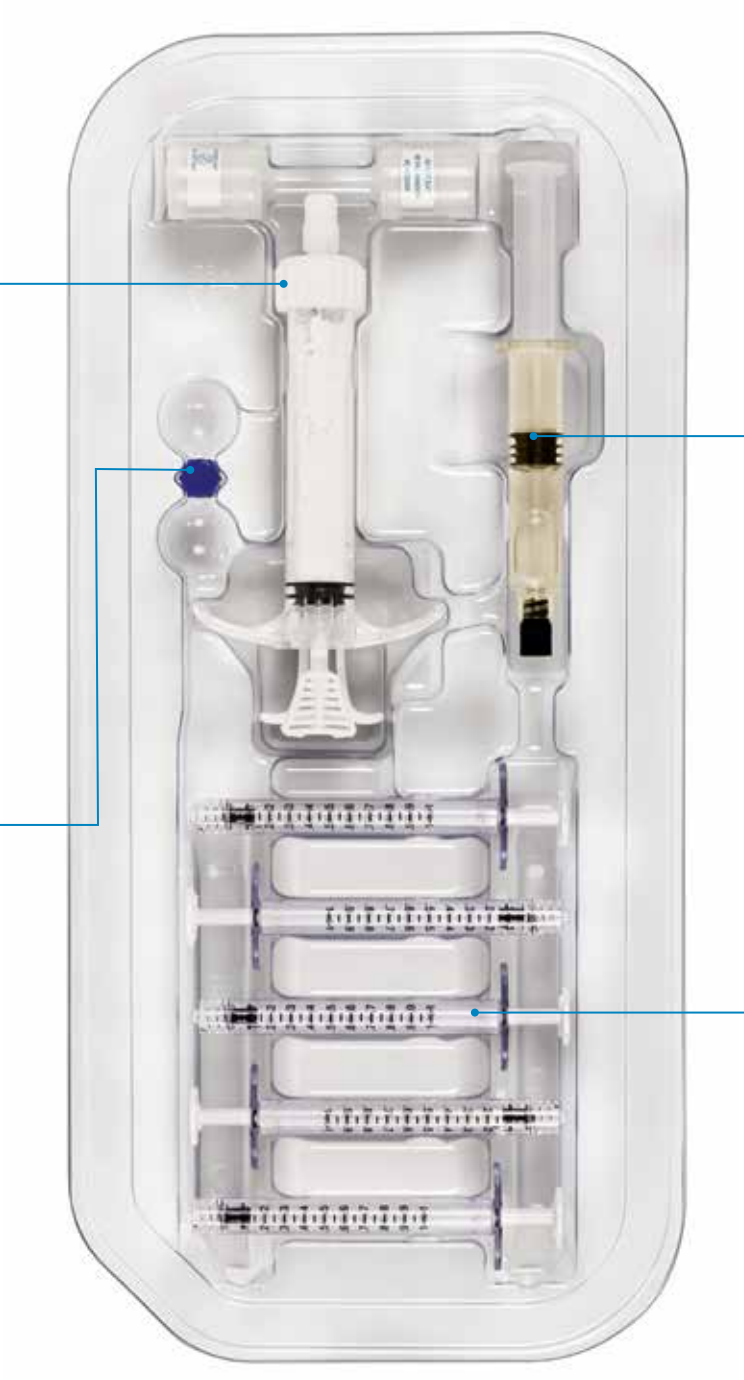
    Connect the first 1 cc syringe. Inject AccuFill BSM into syringe. Repeat for remaining syringes.

    Transfer the desired number of syringes to the operative field (please refer to suggested volumes by indication).

Implant Placement: Filling the Bone Defect (cont.)

Mixing Option 2: Using the AccuFill Pre-Fill (PF) BSM Kit

AccuFill PF BSM is hydrated and mixed before injection, using normal saline (0.9%), or whole blood. The material is mixed in a closed system using the prefilled mixing syringe. Working time for AccuFill PF BSM is approximately 15 minutes (maximum time between mix and injection). Mixed material will not set until injected into the patient.



Implant Placement: Filling the Bone Defect (cont.)

AccuFill PF BSM Mixing Technique

Hydrate:

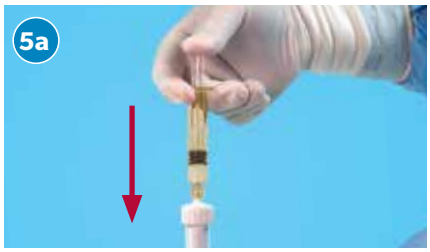
1. Transfer the tray to the sterile field (back table). Remove the AccuFill PF BSM prefilled mixing syringe from tray. Pull on plunger tab to extend the stem completely from within the syringe.

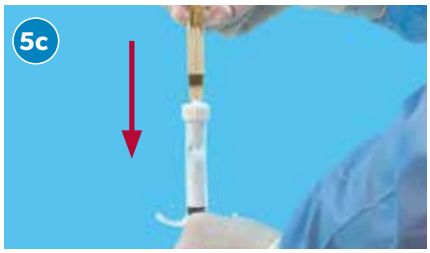
   NOTE: Before connecting the saline syringe, lightly tap on the full prefilled mixing syringe to loosen the AccuFill Powder, which can get compacted.

2. Remove and discard the plug from the prefilled mixing syringe.
3. Remove the prefilled saline syringe from tray. Remove and discard the plug.
4. There is no need to expel air from the saline syringe. Holding the mixing syringe vertically, connect and tighten the saline syringe to the mixing syringe. See image for correct orientation.

   NOTE: To avoid expelling saline, do not expel air from the prefilled saline syringe.

5. Holding the syringes vertically, inject full volume of saline down into the mixing syringe (5a). Pull up on the saline syringe plunger to pull excess air into the syringe (5b). Inject again, to ensure **ALL SALINE FLOWS INTO POWDER** (5c). Repeat to release pressure before removing saline syringe.
6. Attach and tighten the blue LUER lock plug onto the mixing syringe.



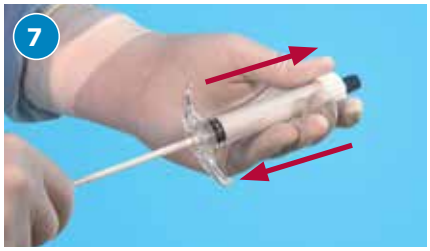


Implant Placement: Filling the Bone Defect (cont.)

AccuFill PF BSM Mixing Technique

Mix:

7. Push the syringe plunger completely in and then pull back and push plunger through the full length of the cylinder to evenly distribute the saline and thoroughly wet the powder.
8. Repeatedly push, pull, and twist the plunger through the material in the syringe and continue for a minimum of 60 strokes/60 seconds. The material must be mixed completely.
   - **NOTE:** Push and pull the plunger completely until it stops at each end of the syringe while twisting at least a quarter turn each time.
   - **NOTE:** Visually confirm through the syringe barrel that the material is being mixed completely. It will have a paste consistency.
9. After the material has been mixed thoroughly, pull on plunger tab to extend the stem fully from the mixing syringe and attach the plunger sleeve onto the stem.



Transfer:

10. Remove the blue luer lock plug from the mixing syringe cap. Holding the mixing syringe with the white cap upright, expel excess air from the syringe. Connect the first 1 cc syringe. Inject AccuFill BSM into the syringe. Repeat for the remaining 1 cc syringes.
11. Transfer the filled 1 cc syringes to the operative field. Implant immediately for the best handling characteristics.

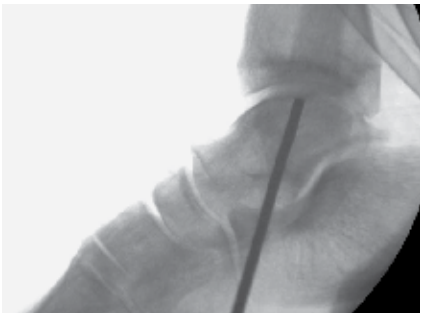
Implant Placement: Filling the Bone Defect (cont.)

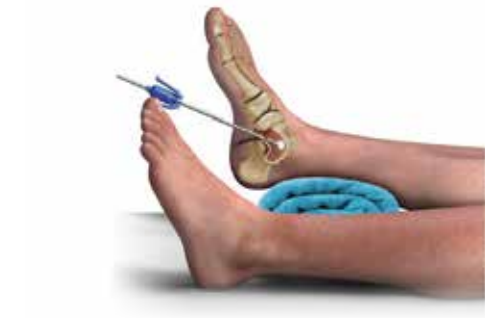
Injecting AccuFill BSM Implant

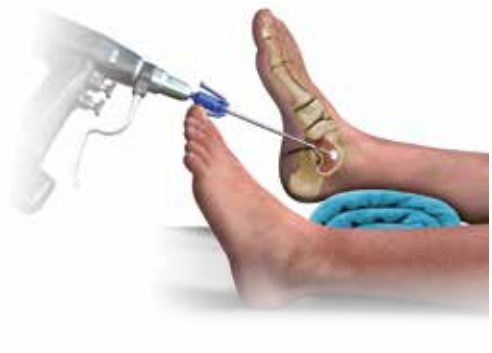
- Confirm AccuPort Cannula placement with AP and lateral fluoroscopy. If using the 11 ga side-delivery cannula, manually rotate the cannula to direct flow toward the defect, as identified by the white line on the hub of the cannula.
- Remove the inner stylus: while holding the cannula body securely with one hand, squeeze together the stylus locking wings with the other hand and pull the stylus out. Set the stylus on the sterile field (Mayo stand or back table)—DO NOT DISCARD!
- Attach the first 1cc syringe of AccuFill mix to the cannula hub; firmly tighten the luer-lock connector.
- Inject the AccuFill BSM using steady manual pressure.
- Remove the first syringe and repeat until desired volume has been implanted. For most procedures, between 0.5 to 2 ccs will fill the defect.
- Reinsert the stylus back into the cannula to inject residual AccuFill BSM. Insert the stylus fully until locking wings are secured to the hub.
- Leave the cannula in place while the AccuFill BSM sets. The stylus/cannula should be left in the bone for 10 minutes to minimize potential for extravasation of unset material.
- Remove the cannula: reconnect the wire driver to the cannula stylus; use reverse torque while pulling back.
- Ensure no excess bone substitute emerges from the insertion portal. Using fluoroscopic imaging, ensure that AccuFill BSM is properly placed. Seal all incisions.

NOTE: It is recommended that the scope be reintroduced into the ankle after the AccuFill BSM injection is completed to look for evidence of extravasation of the BSM into the joint. Although uncommon, if extravasation occurs, the material should be removed from the joint using the shaver and irrigation.

NOTE: Reminder to use the T1 image as a reference for targeting accuracy and volume.







Implant Placement: Filling the Bone Defect (cont.)

Injecting AccuFill BSM Implant

Operative Tip:

When attaching and removing 1cc syringes from the cannula, grip the hub firmly to avoid rotating the cannula.

For the 11 ga AccuPort Cannulas, the first 0.7 cc of AccuFill BSM fills the cannula itself; once the BSM fills the cannula and starts flowing into the subchondral cancellous bone, back pressure will increase. Release digital pressure and then slowly reapply it until the material starts to flow again.

For the 15 ga AccuPort Cannulas , the first 0.1 cc of AccuFill BSM fills the cannula itself.

Monitor flow and volume of the AccuFill BSM into the trabecular bone under fluoro. If the AccuFill BSM material is not readily seen on the C-arm monitor, contrast between bone and BSM may be improved by manually changing fluoroscopy settings more toward Bone X-ray settings (decreasing KVP and/or increasing MA) or switching between normal image and "negative".

NOTE: The stylus/cannula should be left in the bone for 10 minutes to minimize potential for extravasation of unset material.

CAUTION: Always confirm AccuPort Cannula position with AP and lateral fluoroscopy before injecting!

- Verify that cannula is completely inside the bone.
- Commit to 1st trajectory; avoid creating 2nd path and potential for extravasation.
- If undesired trajectory is created:
  - Do not redirect cannula inside the bone; the cannula could break.
  - Leave 1st cannula in bone to block backflow; then insert a new cannula along a different path.

CAUTION: It is important to avoid applying bending stresses to the cannula while manipulating the foot and ankle during scoping, to minimize the potential for cannula damage.

CAUTION: Do not overfill the defect site. Over-pressurizing the defect may lead to extrusion beyond the site of intended application and damage to surrounding tissues. Remove any excess material from the subcutaneous tissue at the entry point by gently expressing and irrigating the material. Blot any excess material from the surgical wound as needed.

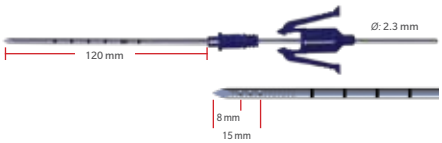
Implants and Instruments

AccuPort Delivery Cannulas

AccuPort Cannulas consist of two components that connect to make one instrument. All cannulas are trocar tipped for cutting ability, and include a stylus that locks to the cannula to allow self-drilling insertion using a standard OR wire driver. AccuPort Cannulas are available in 15 ga (1.8 mm OD) and 11 ga (3.0 mm OD) sizes.

AccuPort End- and Side-Delivery Cannulas 11 ga, 3.0 mm OD

- 120 mm drillable length with etched markings every 10 mm.
- 3.0 mm OD, 2.4 mm ID.
- Commonly used in distal tibia, hind foot, and larger midfoot bones.
  – End-delivery more commonly used in hindfoot indications, but side-delivery can be beneficial depending on defect location.

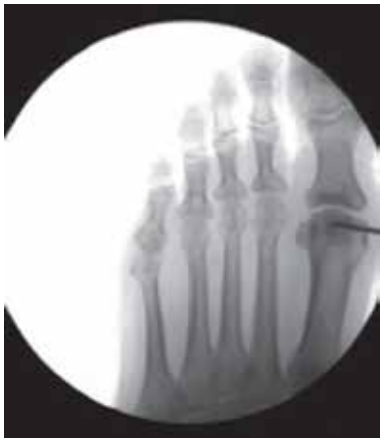


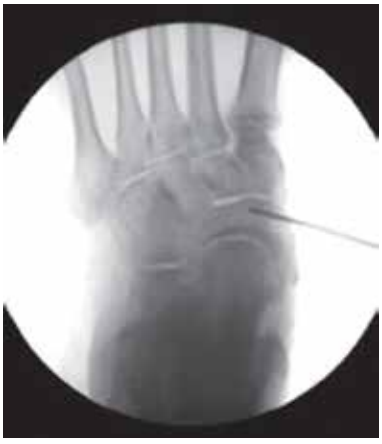
FRONT

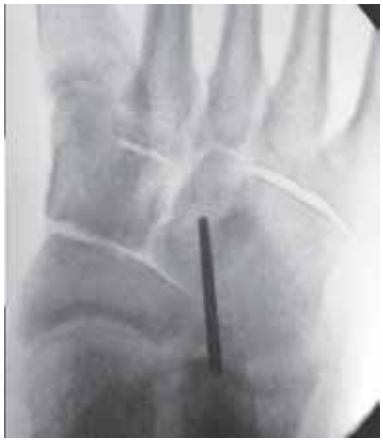
BACK

AccuPort End-Delivery Cannula 15 ga, 1.8 mm OD

- 60 mm drillable length with etched markings every 5 mm.
- 1.8 mm OD, 1.4 mm ID.
- Commonly used in small bones, including midfoot and forefoot.
- Can be used for any defect where a 60 mm drillable length is adequate.







Intraop images of 15 ga AccuPort End-Delivery Cannula.

Ordering Information

Product	Description	Part Number
	**AccuPort Side-Delivery Cannula; 11 ga (3.0 mm OD), 120 mm Drill Length**	307.032
	**AccuPort End-Delivery Cannula; 11 ga (3.0 mm OD), 120 mm Drill Length**	307.034
	**AccuPort End-Delivery Cannula; 15 ga (1.8 mm OD), 60 mm Drill Length**	308.151

SCP Prefill Kits (Packaged with AccuPort Cannula)

Product	Description	Part Number
  3 cc	**SCP Prefill Kit, 3cc Side-Delivery, 11 ga (3.0 mm OD) x 120 mm**	464302
	SCP Prefill Kit, 3cc End-Delivery, 11 ga (3.0 mm OD) x 120 mm	464303
	SCP Prefill Kit, 3cc, End-Delivery, 15 ga (1.8 mm OD) x 60 mm	514153

SCP Complete Kits

Product	Description	Part Number
	**SCP Complete Kit, 3cc Side-Delivery, 11 ga (3.0 mm OD) x 120 mm**	514.302
	SCP Complete Kit, 3cc End-Delivery, 11 ga (3.0 mm OD) x 120 mm	514.303
	SCP Complete Kit, 3cc, End-Delivery, 15 ga (1.8 mm OD) x 60 mm	514.315

AccuMix Mixing System

Product	Description	Part Number
	**AccuMix Mixing System**	311.100

All new Zimmer Knee Creations products introduced after December 1, 2018, will have six-digit part numbers with no decimal point between the third and fourth digits. This is intentional.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professional. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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